## Category #38:

The Guidelines should address the use of hand soaps.

## State Response:

The new standard for Hand Cleaners / Hand Soaps was developed jointly by Green Seal and the Environmental Choice Program[M]. The Green Seal designation of the standard is GS-41 and the Environmental Choice Program[M] designates the standard as CCD-104. The OGS Guidelines will be corrected to reflect that equivalency.

The enabling legislation for the OGS Guidelines defines environmentally-sensitive cleaning and maintenance products as those cleaning and maintenance products that minimize adverse impacts on children's health and the environment. Hand cleaners and soaps may adversely affect the environment. A reasonable standard is readily available (GS-41 / CCD-104), and products certified to that standard are expected to soon be available. Thus, OGS will adopt the GS-41 / CCD-104 standard for hand cleaners.

GS-41/CCD-104 was finalized in June 2006. Products are being accepted for certification by both certification programs. OGS recognizes that products suitable for general hand washing in schools are currently not listed. In recognition of this situation and the fact that the list is unlikely to have many products to choose from for several months, the Guidelines will advise schools that they can postpone purchasing products from these lists until after January 2007. By that time, a reasonable variety of products is anticipated to be available from the certified lists. A sample list of hand cleaners will be developed as products can be demonstrated to meet this standard.

Substantial technical comments and details were submitted opposing the adoption of GS-41 – CCD-104. The following detailed responses are directed to these technical comments contained in Section F below:

**(1)** NYS commends the Soap and Detergent Association (SDA) for partnering with the Centers for Disease Control (CDC) to improve hand hygiene among Middle School children. The School Network for Absenteeism Prevention (SNAP) program is a commendable educational program aimed at increasing awareness of the importance of hand hygiene and improving hand hygiene behavior in school students. The materials available on the program's web site and related links on other web sites (CDC, SDA, etc.) all promote use of soap and water for routine hand washing and the need for thorough washing rather than the misguided reliance on antimicrobial additives to provide the perception of protection. Alcohol-based hand sanitizers, that are not hand cleaners per se and therefore not covered under these guidelines, are recommended for hand hygiene use only in situations where water for hand washing is not available.
*refs: http://www.itsasnap.org/index.asp; http://www.cleaning101.com; http://www.cdc.gov/foodsafety/SNAP.htm*

**(2)** OGS agrees that hand washing is an important element of general hygiene in schools. However, as discussed in more detail below, current evidence does not support the proposition that the use of antimicrobial soap and water for general, routine hand washing outside of health care or food service settings provides a benefit in terms of reduced bacterial load on hands or reduced infection rates compared to hand washing with non-antibacterial soap and water.

The comment asserts that poorly maintained bathroom facilities lacking soap and hot water and locked bathroom facilities often occur in schools. This issue is not directly relevant to the green-cleaning guidelines, as proper provision of restroom facilities in school buildings is already required under SED regulation 8 NYCRR 155.7, which states:

*8 NYCRR 155*
*§ 155.7 Health and safety in existing educational facilities.*

*Facilities in school districts, other than city school districts in cities having 125,000 inhabitants or more, shall meet the following requirements and, in particular instances, such other requirements as may be deemed necessary by the commissioner to insure the health and safety and accident protection of occupants.*

*(e) Water and sanitation.*

*(1) An adequate supply of safe, potable water for drinking shall be dispensed from approved sanitary drinking fountains.*

*(2) Toilet rooms for boys and girls, with flush toilets and wash sinks which are connected to an adequate water supply under pressure, and connected to an approved individual or public sewage disposal system, shall be provided.*

*(3) No source of water supply, nor sewage disposal system, shall be used which has not been approved by the appropriate agency of the State Department of Health or Department of Environmental Conservation*

In addition, the NYS Building Code, based on the international building code and adopted in January 2002, requires the following:

*Section 607 HOT WATER SUPPLY SYSTEM*

*§ 607.1 Where Required. In occupied structures, hot water shall be supplied to all plumbing fixtures and equipment utilized for bathing, washing, culinary purposes, cleansing, laundry, or building maintenance. Tempered water shall be delivered from accessible hand-washing facilities.*

Based on the NYSED-required five-year building condition survey conducted in 2000 – 2001 for NYS schools, fewer than 5% of schools reported unsatisfactory conditions for either water distribution systems or drainage systems in schools and fewer than 10% reported unsatisfactory plumbing fixtures. Only 1 school out of 3017 reported a non-functioning condition for any of these system categories. Therefore, the assertion that lack of functioning toilet facilities is common in schools is not supported in New York State schools.

Anti-bacterial soaps cannot be properly used under the postulated scenario that proper hand-washing conditions (including potable water) are not available, since they require the use of water for lathering and rinsing. Therefore, the suggestion that they are particularly necessary under such conditions is illogical.

CDC Standard precautions recommend using plain (non-antimicrobial) soap for routine hand washing. Standard precautions recommend use of antimicrobial soap or waterless antiseptic for hand hygiene only for specific circumstances such as control of outbreaks or hyperendemic infections that are relevant only to the healthcare setting.

*ref: www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html*

NYSED standard operating procedures for general hygiene and disease prevention in schools recommends general handwashing with soap and water. Waterless antiseptics are only recommended when hand washing facilities are unavailable. These are not hand cleaners per se and are not covered under the proposed Guidelines.

*ref: http://www.schoolhealthservices.org/uploads/Control%20Communicable%20Diseases-August%2018%202005%20final.pdf*

NYSDOH Pandemic Influenza outreach materials for schools recommend use of alcohol-based hand rubs for hand hygiene only when water is not available. These are not hand cleaners per se and are not covered under the proposed Guidelines.

*ref:* http://www.health.state.ny.us/diseases/communicable/influenza/pandemic/docs/pandemic_influenza_plan_edu.pdf

See response **(b)**, above. The specific lack of clarity and sources of confusion are addressed below where they have been identified.

US FDA Non-prescription Drug Advisory Committee (NDAC) concluded by a vote of 11-1 in October, 2005 that there are no populations outside of a healthcare setting in which consumer antiseptic

use has been demonstrated to be more effective than plain soap in reducing infection rates.
*ref: http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4184T1.pdf*

The implication that use of anti-microbial soap for general hand washing is a significant factor in controlling community-acquired infections or "public health threats" is not supported by evidence. Several recent studies of household antimicrobial soaps found no additional benefit in terms of reduced bacterial load on hands or reduced infection rates compared to the use of non-antimicrobial soaps.
*refs:*

*Larson E, Aiello A, Lee LV, Della-Latta P, Gomez-Duarte C, Lin S. Short- and long-term effects of handwashing with antimicrobial or plain soap in the community. J Community Health. 2003 Apr;28(2):139-50.*

*Larson EL, Lin SX, Gomez-Pichardo C, Della-Latta P. Effect of antibacterial home cleaning and handwashing products on infectious disease symptoms: a randomized, double-blind trial. Ann Intern Med. 2004 Mar 2;140(5):321-9.*

*Luby SP, Agboatwalla M, Feikin DR, Painter J, Billhimer W, Altaf A, Hoekstra RM. Effect of handwashing on child health: a randomised controlled trial. Lancet. 2005 Jul 16-22;366(9481):225-33.*

*Luby SP, Agboatwalla M, Painter J, Altaf A, Billhimer WL, Hoekstra RM. Effect of intensive handwashing promotion on childhood diarrhea in high-risk communities in Pakistan: a randomized controlled trial. JAMA. 2004 Jun 2;291(21):2547-54.*

Antiseptic use in the context of first aid and other health care administration and in the context of food service is addressed in the guidelines by giving deference to existing regulations and guidance (e.g., school nurse guidelines, OSHA bloodborne pathogen rule, state sanitary code for food service providers). The adoption of GS-41 / CCD-401 is specifically related to general hand washing.

US FDA regulates antiseptic handwash products as over-the-counter (OTC) drug products under the 1994 USFDA Tentative Final Monograph (TFM). The indication for antiseptic handwashes is "for handwashing to reduce bacteria on the skin" (which may be followed with specific qualifiers such as "after changing diapers"). The TFM definition of antiseptic handwash or healthcare personnel handwash drug product is "An antiseptic containing preparation designed for frequent use; it reduces the number of transient micro-organisms on the intact skin to an initial baseline level after adequate washing, rinsing and drying;…" Based on these definitions, the efficacy of an antiseptic handwash is measured by its reduction of bacterial counts on the skin, not by any effect on infection rates.

On July 8, 2005 US FDA published a review of consumer antiseptic efficacy data submitted by the SDA/CTFA industry coalition (FDA docket # 75N-0183H). USFDA staff summarized the efficacy data submitted by SDA/CTFA and concluded that "overall, the submitted studies do not provide adequate data on which to base a regulatory decision that consumer antiseptics are effective."
*refs: http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4184B1_01_16-FDA-TAB15.pdf http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4184B1_01_06_FDA-TAB05.pdf).*

While it is technically true that the "benefit of antibacterial soaps is still under review" by FDA, the FDA staff review of the SDA submitted efficacy studies and the October 2005 conclusion of the FDA NDAC that consumer antiseptic use has not been demonstrated outside of the healthcare setting to be more effective than the use of plain soap in reducing infection rates are the Agency's most current positions on the state of the science. Both of these reviews support the position that, for general hand cleaning to reduce soil (including transient microorganisms), washing with antiseptic soaps provides no additional benefit over washing with plain soap. Potential risks are associated with widespread use of antiseptic-containing soaps such as environmental accumulation in surface waters, biota and humans and development of anti-microbial resistance. These potential risks, even if small, outweigh the lack of any demonstrated benefit in improved hand washing or reduced infection rates compared to hand

washing with plain soap.

**(5)** The Guidelines (Appendix #4 at (h)) have been corrected to be consistent with the final GS-41 / CCD-401 standard and reads "make no antibacterial, disinfecting, antiseptic or sanitizing product claims." This removes the offending language and should not create any potential confusion about the acceptability of product preservatives.

**(6)** As FDA staff noted in the quoted material above, washing with plain soap and water reduces bacterial levels on hands by roughly 99% in a standardized handwashing test. Few studies have documented that use of antimicrobial soaps for routine hand washing outside of the healthcare setting further reduces bacterial levels beyond the effect of washing with plain soap. Clinical studies of hand hygiene efficacy that show greater reductions of microorganisms with use of antiseptic products compared to plain soap in healthcare settings have used hand-hygiene protocols requiring 15 - >60 seconds of continuous hand-washing exposure to active ingredients (e.g. CDC/HICPAC guidelines, MMWR, 2002, Table 3). These study protocols are not a realistic representation of hand-washing practices expected in the general population, especially in young children. Published studies of hand-washing efficacy in schools have not been designed to separately evaluate the effect of antimicrobial ingredients relative to plain soap, have generally been unblinded, were not properly analyzed for clustered designs and were confounded by multiple interventions in addition to the use of antimicrobial handwash products.

*ref: http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf and FDA refs above*

OGS realizes that FDA has not made any change to the 1994 TFM with respect to antiseptic handwash products. However, under the current TFM the only antiseptic handwash products that are considered generally safe and effective and not misbranded are products containing 60-95% alcohol and 5-10% povidone-iodine, neither of which has hand soap dosage forms. The only other antiseptic handwash active ingredient approved as safe and effective by FDA is chlorhexidine gluconate. Chlorhexidine gluconate products are approved under the New Drug Application program rather than the TFM. No chlorhexidine gluconate products with soap dosage forms were found in the FDA Approved Drug Products ("Orange Book") list current as of May 2006. Other active ingredients in antiseptic handwash products (including but not limited to triclosan, triclocarban, benzalkonium chloride, benzethonium chloride and methylbenzethonium chloride) are listed as Category II (not safe and effective or misbranded) or Category III ingredients ("available data are insufficient to classify as safe and effective, and further testing is required") for safety, effectiveness or both. Under the proposed rule (TFM) they can be marketed despite lacking sufficient data demonstrating safety and efficacy. That was the case in 1994 and the most recent FDA and NDAC reviews for these products indicate that testing data demonstrating efficacy of the Category III active ingredients for antiseptic handwash products have not been produced. If FDA finalized the OTC monograph for antiseptic handwash products based on existing safety and effectiveness data, the products containing Category III active ingredients would become non-compliant without additional data supporting their efficacy.

*refs: TFM ref above (tab15.pdf)*
http://www.fda.gov/cder/ob/default.htm

The regulation of drug products by FDA sets a regulatory floor with respect to safety and effectiveness for products introduced into interstate commerce. The state law mandating use of environmentally preferable cleaning products in schools gives additional authority to OGS within New York State to identify cleaning products that are in the same "form, function and utility" as products currently used by schools but convey environmental benefits such as elimination or reduction of harmful chemicals, reduced packaging or reduced energy consumption in manufacturing, use and disposal. In the absence of any documented benefit to general hand-washing efficacy (i.e., equivalent "function and utility"), elimination of unnecessary exposure to and disposal of chemical additives in hand cleaning products is consistent with the intent of the legislation.

**(7)** The lack of evidence for a benefit of antimicrobial soaps in reducing transient microorganisms on the skin beyond that seen with plain soap and water in non-healthcare related environments has been described in detail above. The FDA docket information referred to is generally not relevant to general

handwashing effectiveness in a school environment. For example, clinical handwashing studies following FDA protocols use a 30-second handwashing contact time, followed by 30 seconds of water rinsing, which is not representative of typical handwashing behavior in school children. SED/DOH/CDC handwashing guidelines for school hand hygiene as part of infection control programs is 15 - 20 seconds contact time, followed by water rinsing for an unspecified time period.
*see refs above for TFM and SED infection control guidelines*

Despite SDA's belief that a benefit associated with antiseptic handwash products outside of the healthcare and food preparation environments "will be perceived," current FDA staff and NDAC conclusions, as cited above, appear to be to the contrary based on existing data.
*see refs above for FDA staff and NDAC documents*

**(8)** OGS recognizes that special cleaning practices are prescribed by existing laws, regulations or guidance. The law for environmentally sensitive cleaning products does not supersede or change existing public health, labor, education and environmental conservation regulations and guidance related to cleaning and maintenance practices. In certain locations (e.g. food service areas and nurses offices) and for special circumstances (e.g. blood spills) different products and practices may need to be used to satisfy the requirements of existing regulations. Several examples of relevant regulations and guidance were made publicly available in the "FAQs for Legislation" fact sheet on the OGS website prior to the release of the draft guidelines. This information has been incorporated into the guidelines.

Regarding the specific comments about handling animals, the risk of a serious *E. coli* infection from handling animals is well-documented, but did not occur at the New York State Fair in Syracuse. Currently, CDC and DOH recommend washing with soap and water and do not suggest the use of antimicrobial soaps. For example, "Persons should always wash their hands thoroughly with soap and water after handling reptiles and amphibians or their cages." (MMWR Dec 2003).
*refs:*
*R. Gage, et al. Outbreaks of Escherichia coli O157:H7 Infections Among Children Associated With Farm Visits – Pennsylvania and Washington, 2000. MMWR 2001; 50:293-297.*

*B Warshawsky, I Gutmanis, B Henry, et al. An outbreak of Escherichia coli 0157:H7 related to animal contact at a petting zoo. Can J Infec Diseases & Med Micro 2002; 13[3]:175-181.*

**(9)** The single triclocarban study that SDA criticizes in its comments as flawed because of its lack of representativeness does not provide a balanced summary of the weight of evidence for the environmental presence of antiseptic active ingredients in waste water treatment plant (WWTP) effluents and surface waters. A literature review conducted by FDA staff shows that many studies have detected triclosan in WWTP effluents after completion of wastewater treatment and in natural surface waters (i.e., not in raw sewage). Examples exist of surface waters with detectable triclosan that have no WWTP effluent inputs (e.g., New Orleans storm-water collection canals, although they might be susceptible to influence from aging sewer lines). Two studies report detecting triclocarban or both triclocarban and triclosan in river water, wastewater and WWTP effluent in the Baltimore area (presumably the study (or studies) criticized in the SDA comments). River water samples in those studies were collected upstream of WWTP outfalls, but the authors acknowledge that some (not all) sample locations were selected based on existing knowledge of influence from leaking sewer lines. Although this is not a purely random sampling design, it points out that surface waters can be affected by the presence of these compounds in wastewater due to infrastructure deterioration.

Laboratory studies demonstrate that photodegradation products of triclosan can include low-chlorinated dioxin congeners and di-chlorophenol and that triclosan can react with free chlorine in water to form chloroform. Limited field evidence suggests some potential for triclosan to bioaccumulate in fish. Triclosan can be methylated in the environment, and methyltriclosan was found to have a fish bioconcentration factor similar to other persistant organic pollutants in one study. One limited study found detectable triclosan in three of five human breastmilk samples.

Laboratory and field studies of effects of triclosan on aquatic organisms (including algal and

bacterial community structure) reviewed by FDA staff suggest that observable effects on microbial community structure and growth, development and survivorship of various aquatic organisms occur at concentrations that are often above levels detected in surface waters, but the range of observed effect levels and the range of observed surface water concentrations overlap.

Although data on the potential for adverse environmental effects for antiseptic active ingredients is limited, examples of this chemical category are detectable in environmental media, including biota. Some also have lipophilic and low volatility physical chemical properties suggesting a propensity to accumulate in sediments and food chains. In the absence of clear benefits associated with the use of these drug active ingredients for general purpose handwashing, any addition to the environmental load of these chemicals from this use appears unjustified in terms of balancing potential risks with negligible benefits.

*refs: FDA background documents for NDAC Oct 2005 meeting –*
*http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4184B1_01_00-FDA-TOC.htm*

**(10)** The guidelines did not raise antimicrobial cross-resistance as a specific concern related to hand cleaners, and therefore a response to this comment is unnecessary. However, a relevant FDA staff literature review of biocide-antibiotic cross-resistance (web link below) provides a more reasonable representation of the current state of knowledge and concern. Based on the FDA review, OGS cannot conclude with certainty that no cross-resistance will occur. Therefore, even a small risk of contributing to antimicrobial resistance should be avoided, given the lack of demonstrated public health benefit from antimicrobial use in routine handwashing.

*refs:*
*FDA background documents for NDAC Oct 2005 meeting –*
http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4184B1_01_00-FDA-TOC.htm

**(11)** Peter Gilbert and Andrew McBain did conclude, in the May 2004 issue of *Microbiology Today,* that the risks of antibiotic resistance from biocide use may have been overstated, but they did not draw the conclusion attributed to them in the comment that health and hygiene are being compromised as a result. Their main conclusion in the 2004 article was consistent with their conclusions in an earlier paper:

> *"What should we be doing? We should limit our use of those antibacterials to applications where there is demonstrable gain and a proven need for hygiene in that application. We should certainly not abandon good hygienic practice. We should use antibacterials that lose their effectiveness rapidly once they are diluted from the point of action; we should not be mis-using recalcitrant molecules that can build up in the environment."*

*ref:*
*Gilbert, P and McBain, AJ (2001). Biocide use in the domestic setting and concern about antibiotic resistance. J Infect 43:85-91.*

The product endorsed in the last comment is a hand sanitizer, not a hand cleaner, and its use is therefore not addressed by these Guidelines. The product's active ingredient has not been shown to be generally recognized as safe and effective under the FDA TFM process (See response in d (6) above). For such products to be effective, hands should be clean before the sanitizer is used, and the product label clearly notes this requirement.

## Frequently Asked Public Comment:

Hand Soaps

A. The provisions that apply to antimicrobial hand soaps should be deleted. Given current and future public health challenges, we believe that it would be prudent for New York educators and students to have all available tools to combat known or suspected health issues.

Based in Washington, D.C., CTFA is the trade association representing the cosmetic, toiletry, and fragrance industry in the United States and globally. Founded in 1894, CTFA has a membership of nearly 600 companies including manufacturers, distributors, and suppliers of the vast majority of finished personal care products marketed in the United States. We have over 100 members that are either headquartered or have manufacturing facilities in New York State.

Antimicrobial hand soaps are valuable for infection control in public buildings, homes, schools, and daycare situations. Antimicrobial had soaps provide a public health benefit by reducing or eliminating bacteria on skin. These products are helpful for the general population to reduce the risk of infection or acquisition of disease. Given the increasing role that schools play in our society, educators should be able to purchase and use antimicrobial hand soaps that are as effective as those used in homes, offices or professional healthcare settings.

Furthermore, the use of antimicrobial hand soaps in the home or school setting does not contribute to development or resistance or cross-resistance with antibiotics. There is no clinical real-world evidence of increased resistance and/or cross-resistance under current conditions of topical antimicrobial products. Programs exist in the U.S. to monitor the possible emergence of antimicrobial resistance. These include the National Nosocomial Infection Surveillance (NNIS) program and the interagency Task Force on Antimicrobial Resistance. Extensive data on the environmental safety of individual active ingredients exist. Appropriate margin of safety values have been established and are available for public inspection. (Michael Thompson, Senior Vice President, Government Affairs Cosmetic, Toiletry, and Fragrance Association, CTFA)

B. Current law does not require custodial products such as toilet paper, facial tissue and hand soaps to meet environmentally sensitive criteria. The statute only refers to "cleaning and maintenance products." While we appreciate OGS' recommendations in this regard, districts should not be limited to purchasing products that meet specific standards.
(Diane S. Ward, Governmental Relations Representative, NYS School Boards Association)

C. I am aware that on the OGS draft purchasing guidelines, there is guidance on how to purchase paper products and hand soaps. I am not aware that the original education law covered paper products and hand soaps. Can you tell me if these 2 items are now considered covered by the intent of the education law and are REQUIRED by law to be purchased using environmentally sensitive guidelines or is it up to the school district to decide if it wants to purchase these products following the green guidelines OGS will provide. (Michele Casale, Environmental Health and Safety Specialist Broome Tioga BOCES, Endicott NY)

D. Item V, sub-item 3. GS-41 standards. The GS-41 proposed standard for hand soap has not been finalized, and is still going through consensus review. Once this standard is approved, it will take approximately 12-18 months to achieve certification status, based on existing GS certification patterns over the last 2 years (based on our experience), and to get product into the pipeline for sale. This is due to many factors, including, formula prep, formula review, label review, manufacture, marketing, costing, distribution. We ask that if a GS-41 approved hand soap is included as part of the bid procedure, that suppliers be given a 12-18 month window to develop and market a product for sale. (Chuck Hodge, Scientist, Ecolab Inc., Eagan, Minnesota)

E. Comments on Section V.B2.

- The Green Seal GS-41 Standard is considered fully equivalent with the Environmental Choice standard for Hand Soaps and this equivalency should be noted in the heading.

(Lauren Heine, Ph.D., Dir. Applied Science, GreenBlue, Charlottesville, VA)

F. The Soap and Detergent Association is a 109-member national trade association representing the formulators of soaps, detergents, general household cleaning products, industrial/institutional cleaners, and the companies that supply ingredients and packaging to the formulators.

SDA commends New York State's efforts to provide a healthful environment for New York State schools. This is a goal which SDA shares with the State. As the home of the U.S. cleaning products

industry, SDA is dedicated to improved health through improved personal hygiene and environmental cleaning. This commitment has been part of SDA's Mission since its founding in 1926.

SDA's main concerns are:

• The proposed avoidance of hand soaps containing antibacterial ingredients is inappropriate and unjustified in view of their demonstrated ability to kill and inhibit bacteria on the hands.

Hand Soaps – Green Seal 41

Of particular interest to SDA are the provisions related to hand soaps (page 11-12). For several years, SDA has partnered with the Centers for Disease Control and Prevention (CDC) on a hand hygiene program targeted at Middle Schools that has helped reduce absenteeism rates in thousands of schools across the country. To our knowledge this is the first co-branded program undertaken by the CDC with a trade association like SDA. The logos of the CDC and SDA appear side-by-side on all of the program materials.

For SDA, hand washing is about health. Proper hand washing is essential to breaking the chain of infection in schools as well as other public and shared environments such as public buildings, senior citizen and child day care centers. SDA's experience is that the restrooms in schools are often poorly maintained and often not supplied with soap and hot water. In addition, students don't have access to soap and water because the bathrooms are locked. Especially under these conditions, anti-bacterial soaps are particularly important because proper hand washing conditions are not available Moreover, the proposed ban on antibacterial soaps needs to be rethought in view of the potential avian flu pandemic and similar public health threats.

In general, SDA finds me draft GS - 41 to be unclear and rife with confusion. Moreover, SDA understands that the Green Seal approval process for this standard has not been completed. Therefore, it is inappropriate to cite it in the context of these guidelines. These factors alone should disqualify it as an appropriate standard. Our concerns are addressed in depth below.

The proposed guideline (page 16) states that:

> "New York State is avoiding the use of hand soaps with anti-bacterial additives since the Center for Disease Control (CDC) recognized that they do NOT add to the protection of public health in general hand washing circumstances, and the environmental community is concerned about the effect these biocides might have once they enter the environment."

SDA respectfully urges that any prohibition against the procurement and use of anti-bacterial hand soaps be deleted from the final guidelines. Moreover, as we hope to demonstrate, there are numerous instances in the school environment which do not come under the heading of "general handwashing." Finally, the benefit of antibacterial soaps is still under review. The multi-sector approach being undertaken by the Food and Drug Administration (FDA) is germane in this instance.

We have enclosed, for your consideration, examples of official regulations, guidelines or recommendations for the use of topical antimicrobial products. Included are recommendations from Public Schools in New Jersey and Oklahoma, as well the National Federation of State High School Associations, which includes a rule that antibacterial soaps and wipes should be available during athletic events.

At (h) (page 25), the standard states that the product:

> "...not be formulated with antibacterial ingredients nor make antibacterial, disinfecting, antiseptic or sanitizing product claims... or the need to be registered under the united States Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)."

This criterion creates wholesale confusion and only emphasizes the need to put it aside.

*Product Preservatives* (page 25)

The requirement that no "antibacterial ingredients" needing to be registered under FIFRA be present in the soap poses a potential problem. To our knowledge, the only "antibacterial ingredients registered under FIFRA that would be used in hand soaps are preservatives. Given their organic nature, hand soaps cannot maintain shelf life without the use of preservatives to prevent bacteria and/or fungal growth. The function of these preservatives is biostatic. And there is a wide range of biostatics approved by EPA and PMRA that perform this function. Banning the use of these preservatives effectively bans all soaps. It is essential that the use of preservatives not be prohibited.

Hand soaps making antibacterial claims are regulated by the Food and Drug Administration (FDA), not the EPA which administers FIFRA. Coverage by FIFRA would require the products to be registered as "pesticides." Consequently, the citation to FIFRA in the GS-41 draft standard is confusing.

SDA is also concerned with the reference in GS-41 to Health Canada's Therapeutic Products

Directorate. It seems basic to us that all references for products sold in the United States should be to United States' law and regulation.

*Antibacterial Soaps -Efficacy* (page 25)

There is overwhelming evidence that use of antimicrobial-containing hand cleaners does reduce the biological load of illness-causing bacteria on hands. Whereas the FDA Nonprescription Drugs Advisory Committee (NDAC) and other authoritative bodies have recently called for additional information to substantiate the effectiveness of antimicrobial agents in hand cleaners to reduce disease, it would be premature for New York State to eliminate the use of this entire class (or any entire class) of chemicals from the accreditation standard without having sufficient information/data to make a scientifically-based decision. Given that the FDA has not made any change to the way in which it regulates antimicrobial hand soaps, it is recommended that New York State follow the FDA lead and not take the premature step of setting additional and arbitrary restrictions on institutional hand cleaners.

Further, referring to the definition for "Antimicrobial" as an "agent that kills microbes," (page 31), this definition could include the surfactants in soaps as they disrupt the cell walls and other structural components of microorganisms. That is, the soap alone can have some antimicrobial effect simply because of its alkalinity. However, antibacterial claims are not made on the basis of these effects. This is simply the chemistry of basic soap.

The definition, as proposed, could potentially cover all hand soaps, thereby banning all soaps. Any discussion of the benefits and environmental impact of the products has to be more focused than is indicated in the draft guidelines. Certainly, for environmental impacts the analysis should be specific to the active ingredient. The statement of reason for the proposed prohibition is simply inappropriate. The regulation of antibacterial soaps is complex and must be approached carefully to avoid unintended consequences. SDA looks forward to discussions with the Office of General Services to clarify both the regulatory and scientific issues in order to avoid unintended consequences that could have an ill effect on public health.

Benefits of Antimicrobial Soaps

The purpose of antimicrobial active ingredients such as triclocarban (TCC) and triclosan (TSC) in these products is to supplement the capability of the soap/cleaner to reduce the microbiological flora on the skin. In this regard, it is well documented that these antimicrobial ingredients are efficacious and the treated product outperforms untreated product (soap alone). For example, efficacy data on triclocarban (TCC) are publicly available and include extensive minimum inhibitory concentration (MIC), time kill, and clinical hand-wash study data. Internet links to these public FDA-held dockets are:

- http://www.fda.gov/ohrms/dockets/dailys/01/Dec01/122801/75nl83h.pdf
- http://www.fda.gov/ohnns/dockets/dailys/03/Sept03/090203/75n-0183h-c000077-01 -vol 156.pdf

We would also point out that FDA has broken its regulatory approach into three principal sub categories: healthcare, food preparation, and consumer products. This segmentation was undertaken in recognition that there are different levels of concerns with respect to health-related issues in each of the groupings. We cite this because the modem school is not just a learning environment but also provides healthcare and food services, as well as the venue for community meetings and events. This multi-function environment does not, however, appear to have been considered in the proposed guideline.

CDC Statement - Lack of Public Health Protection

The issue of "added" protection of antibacterial ingredients raised in the proposed guideline is a question currently before the FDA. A benefit is generally seen for anti-bacterial soaps in the healthcare and food preparation areas, both of which are relevant to the school environment. However, the question of increased benefit of anti-bacterial ingredients in these products, as well as their presence in general consumer use products is under review at FDA. We believe that a benefit associated with these products

will be perceived.

Hand Washing and Health

Schools as Healthcare Providers

A number of health services are performed in New York schools. These range from the typical school nurse's office to school based health centers and clinics. These services are provided by a variety of health care personnel from nurses and nurses' aides to physician assistants and medical doctors. Treatment varies from addressing scrapes and cuts to preventative, primary and acute medical care. Children served range from preschool to young adults.

The proposed guidelines recommend that antibacterial hand soaps be avoided, which would mean that healthcare providers offering medical care in the school setting would not be able to avail themselves of this type of product. The utility and effectiveness of antibacterial hand soaps is well recognized in the health care setting. These types of products should not be denied to health care providers based solely upon their providing care in a school setting.

Schools as Restaurants

Schools also prepare and serve food for students. Foodservice personnel work hard to ensure safe and wholesome food for students. Foodservice professionals make it a priority to see that the meals they prepare and serve are safe for consumption, especially given that the populations they serve, children, are more susceptible than adults to foodborne illnesses. A key to prevention is proper hand hygiene with poor handwashing being the leading cause of infection and illness. An important tool in ensuring clean hands is use of antibacterial soap products, including those developed for foodservice operations. As we understand the proposed guidelines, antibacterial soaps would be denied to food service personnel.

Other School Activities of Concern

Schools may also operate after school programs, whether day care (extended day) or enrichment. Enrichment may include working with or handling substances where added protection might be helpful, such as after handling pets, reptiles or other animals for special programs and activities. New York State has had at least one unfortunate experience with the animal transmission of an *E-coli* infection at the State Fair in Syracuse several years ago.

Schools may also have technical education programs or participate in the Board of Cooperative Educational Services (BOCES) where students take classes in such areas as animal science, cosmetology, commercial food preparation, and emergency medical technician.

As we understand the proposed guidelines, antibacterial soaps would be denied to personnel and students who participate in these types of school activities, where an added layer of protection would be warranted.

Environmental Effects of Anti-bacterial Soaps

The environmental questions that have been raised over some anti-bacterial ingredients in hand soaps are not supported by the weight of evidence. With respect to the environmental questions which have been raised about triclocarban (TCC), it should be noted that there are serious questions about the validity of the conclusions based on the samples used as well as the extrapolations derived from them; the most recent involved research with respect to TCC concentrations in a stream. In the latter case, the samples were not representative because the samples were taken from streams notorious for illegal discharges of raw sewage (up to 99% of the stream flow was raw sewage). Subsequent extrapolations on a national basis are faulty because of the lack of representative data, i.e., up to 99% raw sewage content in their samples, which was subsequently acknowledged by me researchers.

The environmental levels of TSC and TCC are well below those known to cause effects in aquatic organisms.

In other venues, opponents of these products have invoked the "precautionary principle" as justification for proceeding to a ban simply because of the possibilities raised by some reports. This is a misapplication of the precautionary principle as there has been no proof of harm.

Anti-Microbial Resistance Hypothesis

While not raised in the proposed guidelines, the issue of antimicrobial resistance has also been raised with respect to antibacterial soaps. There is simply no evidence that resistance is induced in the real world by these products. The resistance discussion is based on laboratory experiments that were not representative of real world use conditions. There is no substantiation that similar results occur under the conditions that these products were used. In 2002, The Scientific Steering Committee of the European Commission, Health and Consumer Protection Directorate-General issues an "Opinion on Triclosan Resistance," adopted in June 2002, which concluded (copy enclosed);

> "... there is no convincing evidence that Triclosan poses an (sic) risk to humans or to the environment by inducing or transmitting antibacterial resistance under current use conditions."

In the May, 2004 issue *of Microbiology Today,* published by the University of Manchester (UK), researchers Peter Gilbert and Andrew McBain found that the risks of antibacterial resistance developing from antibacterial cleaning products may well have been overstated and that health and hygiene are being compromised as a result.

> "It is now imperative that confidence is restored in products that form an essential part of domestic and hospital hygiene," write the authors. "Hygiene should be emphasized and targeted towards those applications where there is demonstrable benefit (food preparation, care of the elderly and immune-deficient, wound care, infection control.)"

Further, at the 104$^{th}$ General Meeting of the American Society for Microbiology (ASM) in the same month. Professors McBain and Gilbert also presented research showing that:

> "... the risk of bacteria developing antibiotic resistance after exposure to the biocide triclosan may not be as great as previously believed."

Moreover, it is generally agreed that the culprit with respect to anti-microbial resistance is the over use of antibiotic drugs.

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